Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of aromatic massage of lavender and chamomile on anxiety and sleep quality of patients with burns

Protocol summary

Study aim

Determination of the effect of aromatic massage with aromatic oil of Lavender and Chamomile on reducing anxiety and improving sleep quality in patients with burns

Design

Randomized,Semi-experimental study with control group,, with parallel groups,

Settings and conduct

On Iranian adult patients with burns admitted to the wards of women and men, the burn medical training center of Shahid Motahari Hospital affiliated to the University of Iran

Participants/Inclusion and exclusion criteria

Entry requirements Age over 18 years Awareness of time and place Being able to speak and understand Persian language Percentage of burns between 10-45% recorded in the case Skin healthy Skin or back areas Lack of septicemia symptoms with regard to file information It's been 72 hours since burn Lack of physical disability Degree 2 and 3 burns recorded in the case The absence of mental disorder in the past and past recorded in the case No history of asthma and allergies to plants No history of blood pressure and migraine recorded in the file Absence of self-immolation Lack of pregnancy ;Conditions for not admitting to study Sepsis Removal of the skin of healthy legs or back Sensitivity to massage oils

Intervention groups

The control group is under the daily care of the department Massage group with aromatic oils, in addition to daily care of the department, is under aromatherapy massage with aromatic oils of lavender and chamomile The placebo group, in addition to day care, undergoes massage with baby oil

Main outcome variables

The effectiveness of the aromatic herbal remedy with aromatic oil of lavender and chamomile reduces anxiety and improves the quality of sleep in patients with burns, potentially reducing the use of anti-anxiety and hypnotic drugs and this method is a complementary non-pharmacological method for patients. Burn should be recommended.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180120038444N1**
Registration date: **2018-01-27, 1396/11/07**
Registration timing: **prospective**

Last update: **2018-01-27, 1396/11/07**
Update count: **0**

Registration date

2018-01-27, 1396/11/07

Registrant information

Name

Farzaneh Ameri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1000

Email address

ameri.f@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-10, 1396/12/19

Expected recruitment end date

2018-07-10, 1397/04/19

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of aromatic massage of lavender and chamomile on anxiety and sleep quality of patients with burns

Public title
Effect of aromatic massage of lavender and chamomile on anxiety and sleep quality of patients with burns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Awareness of time and place Ability to speak and understand Persian language Percentage of burns between 10-45% recorded in the file Skin healthy areas of the leg or back Lack of septicemia symptoms with regard to file information 72 hours after burn Lack of physical disability Degree 2 and 3 burns recorded in the case Lack of mental disorder present and past recorded in the case No history of asthma and allergies to plants No history of blood pressure and migraine recorded in the file Absence of self-immolation Lack of pregnancy
Exclusion criteria:
The sample's reluctance to continue cooperation Sepsis in the study Removal of the skin in healthy areas of the leg or back during the intervention Sensitivity to massage oils used during the study Patient's death
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization with 4-card blocking
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
14665-354
Approval date
2017-12-09, 1396/09/18
Ethics committee reference number
1396.9413686003

Health conditions studied

1

Description of health condition studied
Burn
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
"The effect of aromatic massage with aromatic oil of lavender and chamomile on reducing anxiety and improving the quality of sleep in patients with burns", the primary outcome is the anxiety score in the Spielberger questionnaire and Pittsburgh Sleep Quality Score.
Timepoint
Anxiety and quality of sleep are performed at the beginning of the study (before the intervention) and three days later (end of the intervention).
Method of measurement
spielberger's anxiety scale, Pittsburgh Sleep Quality scale

Secondary outcomes

1

Description
Heart rate and respiratory rate
Timepoint
Measurement of respiratory rate and heart rate in the first day (before and after intervention), second (before and after intervention) and third (before and after intervention)
Method of measurement

Heart rate with digital pulse oximeter and manual breathing rate with clock aid

Intervention groups

1

Description
Intervention group: Intervention group: Under massage with aromatic chamomile and lavender oil (2 drops of pure lavender essential oil and 2 drops of pure chamomile essential oil, prepared from yellow firm, diluted in 30 cc of base oil of grape seed) on areas with healthy skin (legs Foot, back), 10 to 15 cc for 20 minutes, control group: day care group, placebo group: under baby massage with healthy skin (legs, back), 10 to 15 centimeters C, for 20 minutes
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari Hospital in Tehran
Full name of responsible person
Mostafa Deh Madhayei
Street address
Tehran Province, Tehran, District 3, Vanak، Rashid Yasemi St
City
Tehran
Province
Tehran
Postal code
1454638797
Phone
+98 21 8877 0031
Email
hospital.motahari@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Deputy Research and Technology
Street address
Iran University of Medical Sciences,Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 1021
Email
research@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farzaneh Ameri
Position
Master of Science nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery ,Rashid Yasemi St, Tehran
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 21 4365 1000
Email
Ameri.f@tak.iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farzaneh Ameri
Position
master of science nursing
Latest degree
Bachelor
Other areas of specialty/work

Nursery

Street address
School of Nursing and Midwifery, Rashid Yasemi St,Tehran

City
Tehran

Province
Tehran

Postal code
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Phone
+98 21 4365 1000

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Total non-Identifiable Data, the Potential of the People Sharing

When the data will become available and for how long
Start Access 2018/5

To whom data/document is available
Professors and Students

Under which criteria data/document could be used
-

From where data/document is obtainable
ameri.f@tak.iums.ac.ir

What processes are involved for a request to access data/document
Request Via E-mail and Respond by Email Within one Week To Do

Comments